ANALYSIS OF THE OUTCOME OF SILICONE ORBITAL IMPLANT IN ANOPHTHALMIC SOCKET – A PROSPECTIVE, DESCRIPTIVE STUDY

Dissertation submitted for

MS (Branch III) Ophthalmology

THE TAMIL NADU DR. MGR MEDICAL UNIVERSITY

CHENNAI

MARCH -2008

CERTIFICATE

This is to certify that this dissertation entitled "**ANALYSIS OF THE OUTCOME OF SILICONE ORBITAL IMPLANT IN ANOPHTHALMIC SOCKET – A PROSPECTIVE, DESCRIPTIVE STUDY"** submitted for MS (Branch III) Ophthalmology March 2008, The Tamil Nadu Dr. MGR Medical University, is a bonafide work done by **Dr. Anuja.J,** under our guidance and supervision in the Department of Orbit, Oculoplasty and Ocular oncology of Aravind Eye Care System and Postgraduate Institute of Ophthalmology, Madurai during her residency period from June 2005 to April 2008.

Dr. Usha Kim

Chief. Department of Orbit,
Oculoplasty and Ocular oncology
Aravind Eye Hospital
Madurai

Dr. M.Srinivasan
Director

Aravind Eye Hospital
Madurai

ACKNOWLEDGEMENT

I thank God for having given me the opportunity to work in this internationally reputed institute, Aravind Eye Hospital, Madurai.

I wish to thank all the people who have made this thesis possible.

I acknowledge with gratitude the dynamic guidance and persistent encouragement given to me by **Dr. Usha Kim**, Chief, Orbit, Oculoplasty, Oncology Services, Aravind Eye Hospital, Madurai, for taking keen interest and sharing her ideas throughout the entire study period. Her valuable suggestions and patronage has been a driving force to make this endeavour possible.

I take this opportunity to pay my respects to our founder, **Dr.G.Venkataswamy,** whose dynamism and vision brought about the origin of this great institution.

I deem it an honour to express my heart felt gratitude to **Dr.P.Namperumalswamy**, Chairman, **Dr.G.Natchiar**, Vice Chairman and Director HRD, **Dr. M .Srinivasan**, Director and Chief ,Cornea services, **Dr.P.Vijayalakshmi**, Chief, Paediatric ophthalmology, **Dr. Kim.R**, Chief, Retina services, **Dr.Krishnadas**, Chief, Glaucoma services, **Dr. S. Rathinam,** Chief, Uvea services, **Dr. Haripriya Aravind**, Chief Cataract

services. Their dedicated approach to work has been a perennial source of inspiration. It is indeed, a great privilege to have been trained by all of them.

I would like to thank **Dr.Hadi,** Consultant, Orbit, Oculoplasty, Oncology Services, for his constant interest and guidance throughout this study.

I would also like to thank my patients, the nursing staff of the orbit clinic and theatre for their kind cooperation during this study.

My sincere thanks to **Mrs. Mahalakshmi**, Ocularist, and her staff, prosthetic eye centre, for their untiring support during this study period.

I thank **Mr. G. Saravanan**, statistician and **Mrs.Kumaragurupari**, librarian, for their invaluable guidance.

Last but not the least, I thank my parents, my sister, and my husband, if not for their immense love and unwavering support, I would not have been what I am this day.

CONTENTS

PART-I

PART - II

INTRODUCTION

Although one of the main goals in ophthalmology is to preserve user and maintain the integrity of the eye, it may become necessary to remove the globe in a number of clinical settings. These circumstances includes selected ocular tumors, a globe that has sustained serious trauma and is damaged beyond repair, an eye that is blind from endophthalmitis, a blind and painful eye, or at times a globe that is deformed and not amenable to ocular prosthesis because of discomfort[1], restoration of both comfort and cosmesis are extremely important to the patient who is eager to resume social and occupational functions.

The psychological trauma to the patient from the loss of an eye can be much worse than the physical disability. This is more evident in instance of sudden loss of the globe secondary to trauma or an unsuspected malignancy. Losing an organ that once provided sights depth of perception, peripheral vision colour vision, job opportunities a livelihood, personal self esteem and other necessities is approached with a sense of fear, self consciousness and apprehension[2]. Because of the degree of psychological trauma, almost no other common surgery in ophthalmology requires as much comparison on the part of the ophthalmologist as discussing the preparation for surgery and the patients

post operative appearance and problem, providing emotional assistance in returning the patient to a productive life[3].

Enucleation / Evisceration of non-seeing disfigured or painful eye leaves the patient with an empty or anophthalmic socket resulting in a volume depletion of 7-7.5cm^3 from the total orbital volume of 30 cm^3. In 1885, Dr.P.H.Mules[4], first introduced hollow spherical glass to fill this lost volume for cosmetic restoration. The common problem arising from anophthalmic sokets have been summarized by Tyers & Collins[5] described in the clinical entity of post enucleation socket syndrome. The distinctive clinical features of ptosis / retraction of upper eyelid / of deep superior sulcus, lower lid laxity and enophthalmos in 1983, though the exact aetiopathogenesis ware better understand when Smith et al[6] employed CT scan to study anophthalmic sockets.

Orbital implants are used as fillers following enucleation or evisceration surgeries to replace the lost volume. The complications that followed and occurred in the early implant surgeries have given rise to the usage of a variety of materials in the following years.

The removal of an eye and the management of anophthalmic socket remains a challenge for the ophthalmologist and ocularist. Excellent cosmetic results and long term control of socket problems are difficult to achieve

consistently and the procedure can be emotionally unsatisfactory for the patient and the surgeon. The goal of each of the various procedure is a natural post operative appearance with symmetry, excellent motility and no socket irritation and discharge and the maintenance of maximal anatomic integrity of the orbit. No single procedure answers all these requirements as evidenced by the various congeal techniques advocated over the year[7]. This study aims at analyzing the outcomes following the use of silicone ball implants.

ENUCLEATION & EVISCERATION:

Enucleation:

Indications for enucleation

It can be classified as absolute and relative indications.

Absolute indications are

1. Intraocular malignancy. E.g. Retinoblastoma, malignant melanoma, metastatic tumours.
2. Sympathetic ophthalmia
3. Extensively traumatized globe

Relative indications are

1. Painful blind eye of unknown etiology
2. Phthisis bulbi
3. Deformed cosmetically unacceptable globe. e.g. Staphyloma.

Techniques:

There are 6 main types of primary enucleation procedure.

1. The simplest procedure is an enucleation without the insertion of an implant. This results in a less satisfactory cosmesis.
2. The second type of enucleation procedure is the placement of an exposed integrated implant. This resulted in good motility but the complication

rate such as extrusion, infection were high. This procedure is not followed nowerdays.

3. The third procedure, the implant is inserted within Tenon's capsule with or without the attachment of the recti muscles anterior to the implant or to the implant itself. Implants are also inserted posterior to posterior layer of Tenon's capsule within the fatly tissue of the muscle cone.
4. The fourth type includes the placement of a wrapped implant with several fascia lata grafts or synthetic material surrounding the implant. The extraocular muscles can be attached directly to the wrapped implant.
5. The fifth procedure incorporates dermis fat grafts.
6. At present, the placement of a wrapped hydroxy apatite or polyethylene implant in the state of the art in implant materials but the long term results & complication rate of this procure is unknown.

Advantages of enucleation:

1. The histologic architecture in preserved.
2. The livelihood of cutting through an undiagnosed intraocular tumor is reduced.
3. All the uveal tissue in removed thereby lowering the risk of sympathetic ophthalmia.[8,9,10]

Evisceration:

Evisceration is indicated in

1. Endophthalmitis indicated painful blind eye.
2. Painful / painless or disfigured eye due to absolute glaucoma, uveitis, corneal scarring etc.
3. Globe injured by trauma but with an intact scleral shell in which there is no threat of sympathetic ophthalmia.

Advantages of Evisceration:

1. The meninges and optic nerve are not related thereby reducing the chance of bacterial seeding of the subarachnoid space & development of meningitis.
2. Drainage of the ocular abscess is performed quickly and early with excellent operative exposure and superb visualisation.
3. Excessive bleeding from the inflamed orbital soft tissue is avoided.
4. Sclera remains intact & serves as a barrier the progression of the suppurative process. (although seeding can occur through the emissary & vortex vein)
5. Delicate orbital anatomic structure are not disturbed.
6. Normal orbital physiology and full ocular mobility are anticipated once the infection clears.

7. Globe remains fixed in position by Tenon's capsule, extraocular muscles and the intermuscular septum.

These factors tend to enhance the post operative cosmesis & reduce the burden of long term complications of evisceration compared with enucleation.

Disadvantages of Evisceration:

1. It is theoretically impossible to remove all the uveal tissue from the scleral coat so there exists a potential risk of sympathetic ophthalmia .
2. Unsuspected intra ocular malignancy can be disseminated by manipulation of intra ocular contents.
3. Pathologic evaluation of globe is often incomplete & not satisfactory.

Contraindications:

1. Existence or possibility of an intra ocular tumor.
2. Phthisis bulbi with marked shrinking of the globe.
3. Advanced degeneration of the globe.
4. When pathologic investigation of ocular contents is desired.
5. Patients who have nystagmus may develop bizarre movement with prosthesis
6. Past or present history of systemic malignancy with or without detectable intra ocular tumor.

Techniques:

The procedure may be performed under local or general anaesthesia. Even under general anaesthesia, retro bulbar injection of lignocaine helps reduce bleeding & extend post operation analgesia.

Two techniques are followed:-

1. Evisceration with retention of the cornea
2. Evisceration with keratectomy[8,9,10]

CHARACTERISTICS OF AN ANOPHTHALMIC SOCKET:

The characteristics of the ideal socket and eyelid on the anophthalmic side are:-

1. Centrally placed, well covered buried motility implant of adequate size, fabricated from an inert material.
2. Deep fornices.
3. Inferior lid & cul-de-sae that can support the weight and presence of the prosthesis.
4. Superior lid and supratarsal fold that simulates the normal follow eyelid.
5. An anophthalmic socket that is on the same place as that of the normal side
6. Normal position of the eyelashes.

Changes occurring in the anophthalmic socket:

Irrespective of the surgical technique or modifications used both in enucleation and evisceration surgery, certain changes occur in all anophthalmic sockets. These changes are somewhat less in the post-evisceration state because there is less disturbance of extraocular anatomic structures.

A change in the metabolism and circulatory dynamics of the anophthalmic orbit occurs because a globe with its normal blood supply and metabolic function is no longer present. Thermography studies performed on anophthalmic patients showed colder readings on the anophthalmic side when compared to the normal size. Atrophy of orbital fat is most likely due to the decreased circulation and decreased metabolic requirements of the anophthalmic socket.

There is always some atrophy of orbital fat that is most noticeable in the superior eyelid area where many post-enucleation patients actually develop a deep sulcus that, when compared with the normal side, accentuates an enophthalmic anophthalmic appearance. Atrophy of orbital fat within and outside the muscle cone area also contributes to the amount of enophthalmos present. In an enucleated orbit, the relationships and support of the levator muscle are disturbed. Although Koornneef has shown that orbital structures are supported by septa, displacement and sagging occurs and some degree of ptosis is usually present.[11]

The lower eyelid theoretically is not affected by the surgery of the anophthalmic socket – however, in reality it is. The lower eyelid is a major structural support of the prosthesis, and with the passage of time and the constant weight of the prosthesis, some sagging inevitably occurs. For this reason, it is very important to have as light a prosthesis as possible.

Motility of the prosthesis in the anophthalmic socket dependents primarily on the movement and depth of the fornices assisted by movement transmitted to the prosthesis by the posterior wall of the socket. The fornices are most important and account for the major range of motion of the prosthesis. On looking laterally, the lateral fornix should deepen such that the lateral prosthesis edge falls into the cavity. At the same time, the medical becomes shallow pushing that edge laterally. A similar situation occurs when the individual looks in the opposite direction or up or down. The movement of a prosthesis whose back surface is molded to the irregularities of the posterior surface of the socket is further enhanced by the mechanical push of this socket surface against the posterior wall of the prosthesis as the patient looks in different directions.

Congenitally anophthalmic sockets are always associated with some deficiency of midfacial and bony orbital development. In this condition, also, expansion by progressively larger conformers and prostheses is the procedure of choice, and early reconstructive surgery is contraindicated. In congenital

anophthalmos, a microphthalmic eye pr remnant of the optical vesicle is usually present. Surgical removal is not advised.

After the child has achieved maximum orbital growth and socket development by expansion, then surgical procedures to further expand or modify the socket cavity in order to maintain a prosthesis can be attempted. Theses include mucous membrane grafting and/or split-thickness grafting, reconstruction of the eyelid with ear cartilage and/or sclera to correct an entropion that so often develops, and even osteotomies with bone rearrangement.

The problems associated with the congential anophthalmic socket are less easy to solve than those associated with an anophthalmic socket secondary to adult enucleation. The problems associated with socket development after enucleation during childhood fall between the above two extremes.[12]

ORBITAL IMPLANTS

The qualities of an ideal implant are, that it should some the normal globe as closely as possible. The implant must replace sufficient orbital volume but allow for a prosthesis of adequate anterior chamber depth, have minimal rates of exposure extrusion, infection or inflammation ,be non antigenic & biologically inert while providing socket motility transmitted to the prosthesis to simulate normal globe & socket as much as possible.

The implant should be completely buried and simple in construction without projecting and angulated surfaces that might erode the conjunctiva.

The implant should be light weight, centred within the muscle cone, anchored to orbital tissue to minimize extrusion & migration and be able to be integrated into the extraocular muscles and orbital soft tissues without creating fibrous adhesions of the orbital connective tissues. It should be able to transfer its motility to the prosthesis.

Replacing the lost volume:

Volume loss appears to be the major determinant of post-enucleation anatomic changes, Human radiographic studies have confirmed that placement of a spherical implant within Tenon's capsule counteracts the post-enucleation rotation of intraorbital contents (and associated back-tilt of the prosthesis). This

is true even when the implant is placed late after enucleation. Partial volume replacement permits a thinner prosthesis, thus relieving weight on the lower eyelid and minimizing associated ectropion formation. Traditionally, enucleation is thought to produce about a 7.0-ml loss of orbital volume, based on an average axial length of 24 mm. More recent studies suggest the average volume loss is higher, about 7.5--8.0 ml, emphasizing that there is substantial variability (5.5--9.0 ml). Clearly a myope with an axial length of 28 mm will have a greater loss of volume from enucleation than a hyperope with an axial length of 20 mm. Thus measuring the diameteror water displacement of the enucleated globe may be the most appropriate method of determining implant size. In cases of phthisis and in the absence of a history of significant anisometropia, an A-scan of the contralateral eye may be useful for implant size selection, assuming symmetric bony orbital development and the absence of prior socket contracture.

A 20-mm spherical implant has a volume of 4.2 ml The remaining volume (about 3--4 ml) must be replaced by the prosthesis. However, the physical dimensions of the palpebral fissure and conjunctival cul-de-sac, plus problems associated with lower lid laxity produced by a heavy prosthesis, limit the practical maximum size and volume of the prosthesis. Average prosthesis volume is about 2.0-- 2.5 ml. A recent study suggested that the upper limit of prosthetic volume is about 4.2 ml (in the presence of a small implant).

Interestingly, among patients with implant sizes of 14--22 mm and optimal prosthetic as judged by an ocularist, the average prosthesis volumes were remarkably similar: 2.2--2.3 ml. Thus when a small implant is used, the overall volume deficit (orbital volume loss from enucleation implant þ prosthetic volume]) may be even greater. Placing an implant larger than 22 mm may carry higher exposure rate in the early postoperative period as Tenon's capsule must be closed with greater tension. At the extreme end, a large implant (usually 24 mm) will prevent the ocularist from fitting an artificial eye with enough antero-posterior depth (4 mm) to create a realistic anterior chamber depth. In addition, crowding of the conjunctival fornices could restrict prosthesis movement. In attempt to place larger implants in the enucleated orbit without placing undue tension on Tenon's capsule, placement of the implant posterior to the posterior layer of Tenon's capsule has been advocated; however, practice this may be difficult secondary to tissue edema and access to the deep orbit.[13]

HISTORICAL PERSPECTIVE OF ORBITAL IMPLANTS:

Removal of an eye for treatment of severe ocular disease was first described by George Bartisch more than 400 years ago[14]. A hook was passed through the globe followed by sharp dissection to sever the globe from the orbit. The procedure was performed without an anesthetic and considered

"dreadful" even by standards of that era.[15] The resulting socket deformity was not suitable for fitting with an ocular prosthesis.

It was not until 1841 that the foundation for current enucleation techniques was established in separate reports by O'Ferrall Ana Bonnet. It was more than 40 years later before orbital implants were introduced into modern anophthalmic surgery.[16] P.H.Mules placed a glass spherical implant (the "Mules" sphere) into an eviscerated socket in 1885, and W.A.Frost, 1 year later, introduced a similar implant into Tenon's capsule after an enucleation procedure.[4] The Mules sphere revolutionized anophthalmic socket reconstructive surgery by replacing lost orbital volume and diminishing postoperative socket retraction. Whereas improved techniques reduced problems with these implants, complications including migration, extrusion, and a tendency to shatter with sudden temperature changes led to a search for improved implant materials.[17] Celluloid, sponge, peat moss, agar, petrolatum, rubber, paraffin, ivory, wool, cork, silk, cartilage, fat, fascia lata, bone, animal eyes, and cat gut were among the organic materials suggested for use after enucleation.[18] Vitallium, platinum, aluminum, silver, gold, and wire were inorganic substances tried as orbital implants.[19] By 1941, popular implants, in order of preference, included: carbonized bone balls, ivory, decalcified bone, formalized cartilage, and the Mules glass sphere.[20] Before this time, all implants were completely buried.

In 1941, Ruedemann introduced a combined implant with a posteriorly oriented tantalum mesh and with an anteriorly exposed acrylic prosthetic eye[21]. The posterior portion of the implant – prosthesis was attached to the rectus muscles, and motility and cosmesis were greatly improved over buried implants used before 1941. Shortcomings including a high rate of infections limited the acceptance of Ruedemann's combined implant. Numerous partially exposed, integrated implants with direct attachment to an overlying prosthesis to improve motility were subsequently developed by Culter, Guyton, Whitney, Rolf, Stone, and others[22]. Use of these implants was also hindered by their high incidence of infection and extrusion.

By the 1950s, completely buried implant were again the focus of orbital surgeons. A variety of implant designs were tried with an attempt to indirectly couple the buried implant to an overlying artificial eye by modifying the anterior surface of the implant as well as the posterior surface of the prosthesis. The Allen[23] and subsequently the Iowa[24,25] polymethylmethacrylate (PMMA) implants were the culmination of these investigations into quasi-integrated implants. The Iowa implant used prominent mounds, which were coupled to concavities on the posterior surface of the prosthesis. These mounds were later reduced in size to create the Universal implant, which remains in use by some North American ophthalmologists[26,27].

Despite the initial acceptance of buried, quasi-integrated implants, implantation, fitting, and exposure problems continued to plague these designs. Ophthalmologists turned to simpler buried implants with fewer problems. Although other implant designs continued to surface (Uribe, Iliff and Soll-mid-1960s), they had a limited degree of success.[15,17] Little change occurred over the next 20 years with respect to implant design, and by 1989, spherical implants made of silicone, glass, or PMMA were the implants most widely by ophthalmic plastic surgeons.[28] Spheres on their own or wrapped in sclera or fascia were the implants of choice in more than 80% of primary enucleations, followed by dermis fat grafts and the Iowa/ universal-type quasi-integrated implant.[28]

TYPES OF IMPLANTS:

The various implants can be divided in to 3 groups.

1. Nonintegrated implants
2. Integrated implants
3. Quasi integrated implants

1. Nonintegrated Implants:

Nonintegrated implants contain no unique apparatus for attachments to the extraocular muscles and do not allow in growth of organic tissue into their inorganic substance. Such implants have no direct attachment to the ocular

prosthesis. Materials used as nonintegrated implants include glass, rubber, silicone, steel, gold, silver, acrylic, and polymethylmethacrylate (PMMA).[29] Compared to no implant these devices provide both volume replacement and improved cosmesis.

Imbrication of the rectus muscles in front of a spherical implant imparts motility to the implant and prosthesis. Like a ball-and-socket joint, when the implant moves, the prosthesis moves. Because the ball and socket are separated by layers of Tenon's fascia, imbricated muscles, and conjunctiva, non-pegged implants offer less motility than pegged implants. Allen has suggested and Beard agreed that imbrication of the recti over nonintegrated implants can result in implant migration caused by contraction of the rectus muscles.[29,30] Few studies have proved that there is no significant differences in motility offered by integrated & non-integrated implants.

2. Integrated Implants:

a. Hydroxyapatite:

The hydroxyapatite orbital implant is commonly used during enucleation surgery.[31,32] It is formed from a salt of calcium phosphate that is present in the mineralized portion of human bone. It is reported to be nontoxic, nonallergenic, and biocompatible.[33] Its porous structure allows integation of fiberovascular tissues into the stroma of the implant.[34] The pore orientation in the

hydroxyapatite sphere may influence the degree of vascularization and the poor vascularization might result in implant extrusion.[35] Two common types of the hydroxyapatite implant are the Bio-Eye hydroxyapatite implant (Integrated Orbital Implants, Inc., San Diego, CA) and the M-Sphere cancellous bone implant (IOP, Inc., Costa, Mesa, CA).

Fibrovascular ingrowth and density changes have been assessed by a variety or radiographic techniques, but contrast-enhanced magnetic resonance imaging with surface coil appears to be the modality of choice.[36,37,38]

b. Porous Polyethylene:

Porous polyethylene is another integrated implant material. This spherical implant was approved by the Food and Drug Administration for use in reconstructive surgery in 1985. Like hydroxyapatite, porous polyethylene allows fibrovasclar ingrowth, albeit not as quickly as hydroxyapatite[34,39]. Histopathologic evaluation revealed that the fibrovascular ingrowth extended to the central core of the implant. Advantages of the porous polyethylene device are that it does not require donor sclera or other type of wrapping material, its cost is low in comparison to hydroxyapatite, and the extraocular muscles may be sutured directly to the implant. Porous polyethylene implants are smooth and malleable, which makes implantation easier.[40,41] The device can be implanted in the standard fashion followed by attachment if the extraocular muscles at points approximating the spiral of Tillaux.[41]

3. Quasi-integrated Implants:

A quasi integrated implant are the Universal or MEDPOR Quad-motility implant. The mounded surface of the Universal or MEDPOR Quad-motility implant offers improved motility over a standard sphere and is an excellent choice if improved motility is desired. This implant, however, may be somewhat difficult to put in by surgeons not familiar with their use and/or only using them occasionally. [42]

WRAPPING MATERIALS:

Volume augmentation as well as improved motility, decreased rates of extrusion, and an extra barrier to the environment have been attributed to the use of implant wrapping materials.[43]

1. Donor Sclera:

Donor sclera is the most popular wrapping material. Perry recommends using fresh frozen donor sclera.[44] After thawing, the appropriate cultures of the donor sclera can be taken. The sclera is trimmed and wrapped to fit the implant, with the use of 4-0 or 5-0 nonabsorbable suture. Although donor sclera is readily available, it is expensive and the theoretical risk of transmissible disease exists, including prion disease, which cannot be screened for at this time. No case of human immunodeficiency virus transmission as a result of implanting donor sclera has ever been documented.[45]

2. Autologous Tissue:

Autologous materials for wrapping implants include temporalis fascia, fascia lata, dermis, pericardium, auricular muscle complex,[46] and pericranium.[47] The advantages of these materials in enucleation surgery are that autologous tissues are a living graft, will not elicit a foreign body response, and vascularize rapidly.

Drawbacks to autologous tissue grafts are that harvesting the graft requires additional surgical time.[45,48] Fascia lata is typically taken from above the lateral knee, leaving noticeable scars and occasional muscle belly herniations.[48] Autologous tissue remains a good alternative to banked sclera in selected patients.

3. Synthetic Mesh:

Vicryl (polyglactin 910) is a synthetic knitted mesh that is identical to the material found in Vicryl absorbable suture. Jordan et al reported success with Vicryl mesh, nothing its ease of insertion and attachment of extraocular muscles.[49] An advantage of synthetic mesh is that is eliminates the possibility of disease transmission.

IMPLANT SIZE:

No randomized clinical trials have been used to compare the size and type of implants.[50] Further complicating this analysis was the fact that some used donor sclera wrapped implants, while others used autogenous tissues.[32] Clearly, wrapping increases implant size.

Predicting the correct implant size needed for adequate volume replacement can also be tricky and is most often decided in the operating room. Kaltreider and coworkers have proposed a method in which axial length measurements of the fellow eye are used to select implant size.[51]

Research by Kaltreider et al suggested the use of A-Scan ultrasonography of the fellow healthy eye to provide a tool for correct orbital implant size to replace 80% of the volume removed at enucleation. Further studies have been that the ocular process should not be depended on to increase orbital volume but instead the focus should be on the placement of appropriate sized orbital implant. Recently an algorithm has been developed for use with the above mentioned preoperative method of assessing the optimal orbital implant size through the use of pre-operative A-Scan ultrasonography of the fellow health eye. This method allows space in the anterior socket for an ocular prosthetic volume of 2ml when the orbital implant is placed posteriorly in the intra conal space.

Globe Size (Axial Length – AL)	Enucleation	Evisceration
< 24 mm (hyperopes)	AL -3	AL-4
≥ 24mm (emmetropes & myopes)	AL-2	AL-3
Children	AL-2	AL-3

A scleral wrap adds approximately 1.5 mm to the diameter of the implant.

SURGICAL TECHNIQUES

Enucleation with orbital implant:

Short and long term complications of enucleation surgery are best prevented by meticulous initial surgical technique. The surgery may be performed by either inserting the intra-orbital implant within Tenon's capsule or posterior to the posterior layer of Tenon's capsule within the fatty tissue of the muscle cone.

Insertion of an intra-orbital implant within Tenon's capsule.

When an implant is inserted within Tenon's capsule, the posterior rent in Tenon's capsule is closed with a 4-0 absorbable synthetic or chromic suture. The implant is inserted and the anterior portion of Tenon's capsule separated from overlying conjunctiva. The dissection of anterior Tenon's from conjunctiva is extensive in order to obtain good depth to all of the fornices. Particular care, however, should be taken when dissecting superiorly. In all techniques, a 4-0 silk superior fornix mattress traction suture should be place before the superior separation of conjunctiva and Tenon's. This helps to pull the levator complex out of the way and avoid injury to it. Deep fornices are essential for good motility after surgery, irrespective of the technique.

Insertion of an intraorbital implant posterior to the posterior layer of Tenon's capsule

Tenon's capsule may be divided into an anterior layer and a posterior layer, anterior Tenon's capsule is defined as that portion in front of the exits of the four extraocular rectus muscles and posterior Tenon's as that portion posterior to these exits.

Positioning of the intraorbital implant posterior to the posterior layer of Tenon's capsule within the fatty tissue of the muscle cone, gives better cosmetic and functional results and also minimizes the risk of later complications such as migration and extrusion. This technique also allows for the more comfortable and safer use of a larger implant than would be possible if the implant were inserted within Tenon's.

Evisceration with orbital implant:

The Procedure may be performed under local or general anaesthesia. Two techniques are followed.

1. Evisceration with retention of the cornea
2. Evisceration with keratectomy

CONFORMERS:

It is necessary to choose a conformer that occupies the fornices. It should not be so small that it falls out or so large that it places tension on the wound. Patel and coworkers devised a standardized set of conformers and symblepharon rings that allow the surgeon to find the ideal fit.[52]

Conformers can be left in for 4 to 6 weeks, at which time the patient is ready for prosthetic fitting.[52] This is because the temporary prosthesis functions as a conformer and fast cosmetic rehabilitation improves the patients' psychological well-being.

COMPLICATIONS

The complications of these surgeries can be classified as follows:

A. Intraoperative Complications

B. Postoperative Complications

A. Intraoperative Complications:-

1. Removal of the Wrong Eye[53]
2. Loss of Extraocular Muscles
3. Orbital Hemorrhage
4. Injury to the conjuctiva ,Tenon's capsules

B. Postoperative Complications:-

1. Early complications:
    a. Orbital Hemorrhage and Edema
    b. Orbital Infection
    c. Conformer Extrusion
2. Late Complications:
    a. Lax Socket
    b. Enophthalmos
    c. Superior Sulcus Deformity
    d. Socket Contracture
    e. Implant Exposure and Extrusion
    f. Wound Dehiscence

A. Intraoperative Complications

1. Loss of Extraocular Muscles:

During enucleation surgery, a rectus muscle may be lost and retract into the orbit. The likelihood of this can be minimized by careful placement of traction sutures. In the event that the muscle is lost, it should be searched for among the soft tissues of the orbit.[54] Tenon's fascia can be grasped with forceps in the meridian of the muscle (in a "hand-over-hand" fashion), and the muscle can often be found within this tissue. The search for a lost muscle may require temporary removal of the implant.

2. Orbital Hemorrhage:

Before enucleation, patients should be asked if they are taking anticoagulants. If so, it is reasonable to discontinue them during the preoperative period, if the physician who prescribed this medication agrees.[55] During surgery, careful dissection and handling of the soft tissues can reduce the chance of intra-operative orbital hemorrhage. Retrobulbar infusion of anesthetic with epinephrine also decreases intraoperative bleeding.

Most commonly, if hemorrhage occurs, it is controlled by packing the muscle cone with gauze and applying pressure. If there are identifiable bleeding vessels, cautery may be useful.[56]

B. Postoperative Complications

1. Early Complications:

a. Orbital Hemorrhage and Edema:

Orbital hemorrhage after enucleation is rare and that, when it occurs, it should be treated with compressive bandages.[57] When severe hematomas occur, exploration may be required, and separate incisions may minimize wound dehiscence and fat atrophy. Ecchymosis of the orbit after enucleation is both common and temporary.[54,58]

b. Orbital Infection:

Orbital infection is a rare complication of enucleation, but it can lead to wound dehiscence.[55,59] It can be characterized by chemosis and persistent pain. Meticulous handling of tissues and clean surgical technique combined with systemic and topical antibiotics for at least 5 to 7 days postoperatively will minimize the possibility of infection.[56] Infection may require removal of the implant, local and systemic antibiotics, and then implant replacement.[54,59] Orbital infections may be more common with integrated orbital implants.

c. Conformer Extrusion:

Conformers may dislodge postoperatively, leading to conjunctival prolapse with eventual scarring and shortening of the fornices. The patient must be counseled that when the conformer is removed for cleaning, it needs to be

replaced into its original position. In the event of conjunctival prolapse, cold compresses and pressure patching may be indicated.[60]

2. Late Complications

a. Lax Socket:

The lax socket results from the secondary effects of time, gravity, and the prosthesis in an anophthalmic, volume-deficient orbit combining to stretch the soft tissues of the orbit. It is the most common late complication of enucleation, and it results in downward and anterior migration of the implant. This implant migration causes enophthalmos and deepening of the superior sulcus with superior lid ptosis. To compensate, the patient is often fitted with a larger and heavier prosthesis, which temporarily eases the problem but eventually results in greater downward migration, increased deepening of the superior sulcus, and lower lid laxity.[61,62]

b. Enophththalmos:

Enophthalmos results from a loss of volume after removal of the globe.[63] Attempts at correction have been aimed at restoration of orbital volume. Rose and colleagues proposed that restoration of volume in the volume-deficient orbit be achieved sequentially, first by the use of either a dermis fat graft or implant and then by implantation of a silastic block into the extraperiorbital

space.[61] Using this approach, they achieved a significant reduction in enophthalmos and superior lid sulcus deformities.[61]

c. Superior Sulcus Deformity:

A superior sulcus deformity, which is caused by loss of orbital volume and relaxation of tissues within the orbit,[64] manifests as a deep groove or space between the upper eyelid and orbital rim, giving the appearance of enophthalmos and ptosis.[60] superior sulcus deformity can be corrected by various procedures like introducing a moldable methylmethacrylate subperiosteal implant[65], suturing the levator complex tendon to the periosteum of the superior orbital rim[66], using dermis fat graft[67].

d. Socket Contracture:

Socket contracture comprises a spectrum of disorders ranging from shortening of posterior lamella of the lids to complete obliteration of the fornices with inability to retain a prosthesis.[60] Dortzbach and Callahan identified two types of socket contracture that are not amenable to surgical repair: 1) Sockets that have significant distortion of the lid margins, and 2) sockets that have undergone multiple repairs. The basic principles of repair involve correction of any volume deficit, replacement of mucosal tissue, and eradication of any underlying infection. Attention then is directed toward correction of any lid abnormalities and placement of an implant, if needed.

Contracted Socket Grading & Management

Grade 1 - Shelved inferior fornix.

Management- Fornix deepening suture.

Grade 2 - Absent inferior fornix .

Management- Fornix deepening suture and mucous membrane graft.

Grade 3 - Grade 2 with absent superior, lateral and medial fornices with rounded canthi.

Management- Fornix deepening suture and dermis fat graft.

Grade 4 - Grade 3 with shrunken conjunctiva and lids.

Management- Fornix deepening suture and dermis fat graft with mucous membrane graft and lid surgery .

Grade 5 - Inoperable socket

Management- Extensive socket surgery with muscle transfer and skin/dermis fat graft .

e. Implant Exposure and Extrusion:

Exposure or extrusion is described as a break in the tissue overlying the implant which in severe cases may lead to extrusion of the implant. Poor surgical technique, excessively large implant size, and infection may contribute to the occurrence of implant exposure. Integrated implants have been advocated

to decrease implant migration, improve motility, and decrease exposure.[32] The vast majority of conjunctival exposures occur along the suture closure line. For exposures of less than 3 mm, observation may suffice; however, in larger exposures(more than 10 mm), the use of free autogenous tissue grafts is recommended.[50] Wrapping of the orbital implant, especially autologous tissue, and a multilayer closure reduce the possibility of implant exposure.

f. Implant migration

This is a change in the position of the implant following placement. The Frost-Lange technique which involves imbrication of the recti muscles on the implant is associated with higher incidence of implant migration. Sutring of the recti muscles independently to the implant reduces the risk.[68]

g. Wound Dehiscence:

Conjunctival wound Dehiscence can be managed by conservative therapies, such as topical antibiotics, conjunctival edge freshening, high posterior vaulting of the prosthesis, and scleral patch grafting.[69]

PROSTHESIS

Making of the prosthesis

1. Evaluate the socket with the help of torch light. Ascertain the socket depth, implants if any, and choose a suitable impression tray that matches the socket.
2. Fit the impression tray and check for the cosmetic appearance in the area of the eye and orbital area and ensure about the patient's comfort.
3. Fix the impression tray into the socket and pour alginate paste using syringe. Allow it to dry for 3 minutes and remove the tray with the impression material. Using this impression tray, a wax model is made. Fit the wax model into the patient's socket. Observe the overall appearance of the socket. Then the wax model is taken out and carved to correct the upper lid, lower lid closure by adding or carving the wax.
4. Once the wax model is ready then make a stone mould which will be used for making the acrylic eye with corneal button. . For making the acrylic eye, high grade polymethylmethacrylate (PMMA) powder is used.
5. Hand painting is done on the acrylic eye by seeing the other eye which will look very natural. After painting, a clear coat is given and polished.

REVIEW OF LITERATURE

1. Current trends in managing the anophthalmic socket after primary enucleation and evisceration. Su GW, Yen MT. et al. Ophthal Plast Reconstr Surg. 2004 Jul;20(4):274-80.

The active membership of the American Society of Ophthalmic Plastic and Reconstructive Surgery (ASOPRS) was surveyed regarding primary enucleations and eviscerations performed between January and December 2002. Survey questions included practice demographics, orbital implant use, wrapping materials, placement of a motility peg, reasons for implant choice, and complications encountered. A total of 2,779 primary orbital implants were reported, comprising 1,919 (69.1%) enucleations and 860 (30.9%) eviscerations. The high-density porous polyethylene implant was used most frequently for enucleations (42.7%), followed by coralline hydroxyapatite (27.3%) and nonporous alloplastic implants (19.9%). For eviscerations, the high-density porous polyethylene implant was the most commonly used implant (42.3%), followed by hydroxyapatite (25.9%) and nonporous alloplastic implants (25.7%). The top 3 reasons for implant choice were outcome (69.3%), cost (43.6%), and experience (39.5%). Most implants were either not wrapped (59.8%) or were wrapped in donor sclera (25.2%) or polyglactin mesh (7.2%). Pegs were used in 8.1% of all implants reported. The most frequent

complications encountered for unpegged implants were exposure (3.2%) and infection (0.4%). For pegged implants, the most common complications reported were pyogenic granuloma (13.7%), exposure (5.7%), and discharge (5.7%). They concluded that in managing the anophthalmic socket, ASOPRS survey respondents preferred to use the porous polyethylene implant after primary enucleation and evisceration. Most orbital implants were not wrapped, and most surgeons preferred not to place a motility post or peg in the implant.

2. Exposure rates of wrapped and unwrapped orbital implants following enucleation. Li T, Shen J, Duffy MT.et al. Ophthal Plast Reconstr Surg. 2001 Nov;17(6):431-5.

A retrospective study was conducted on 117 enucleations over a period of 5 years . Data obtained included patient demographics, surgical indication, implant type, attending surgeon, surgical technique, and any reported complications. The primary outcome was presence or absence of implant exposure at the final recorded visit.

Of the 117 identified cases, 29 were eliminated due to insufficient follow-up data. Of the 88 remaining cases, 48 patients received porous implants and 40 received solid acrylic implants. Implant exposure developed in four cases. All exposures occurred in unwrapped porous polyethylene implants (n=2) or porous polyethylene implants wrapped in absorbable material (n=2). All exposures occurred in patients younger than 18 years of age, and 75%

occurred early after trauma-associated enucleation surgery. They observed that the exposure rate of porous polyethylene implants in this study (9%) was found to be comparable to published rates for hydroxyapatite implants. There were no exposures of unwrapped solid acrylic spheres. Unwrapped porous implants in pediatric patients or following trauma-related enucleation may represent an increased risk for postoperative implant exposure. Absorbable wrapping of porous implants may carry the same risk for exposure as no wrapping. They concluded that porous implants wrapped in durable material appear to be as safe as solid acrylic spheres.

3. Orbital implants in enucleation surgery: a report by the American Academy of Ophthalmology. Custer PL, Kennedy RH, Woog JJ, Kaltreider SA, Meyer DR. Ophthalmology. 2003 Oct; 110(10):2054-61.

On the basis of an extensive review of literature they compared the prosthetic and implant motility and incidence of complications associated with porous and nonporous enucleation implants.

They presented that a randomized clinical trial and a longitudinal cohort study detected no difference in implant or prosthetic movement between nonpegged hydroxyapatite porous and spherical alloplastic nonporous implants. Longitudinal cohort studies show that sclera-covered hydroxyapatite implants have higher exposure rates than sclera-covered silicone implants, and unwrapped porous polyethylene implants have higher exposure rates than

unwrapped acrylic implants. Based on one randomized clinical trial,spherical alloplastic nonporous and nonpegged porous enucleation implants provide similar implant and prosthetic motility when they are implanted using similar surgical techniques. Coupling the prosthesis to a porous implant with a motility peg appears to improve prosthetic motility, but there are few available data in the literature that document the degree of the improvement. They concluded that additional research is needed to document the long-term incidence of complications related to porous enucleation implants and associated surgical techniques.

4. Functional and cosmetic relevance of primary orbital implants.

Kohlhaas M, Schulz D. Klin Monatsbl Augenheilkd. 2003 Jun; 220(6):418-22.

A prospective study was conducted on 20 patients without and 32 patients with orbital implants over 6 to 14 years after enucleation. Maximum prosthesis motility in 4 directions, width of the palpebral fissure and vertical difference of the eye axis were measured using Kestenbaum glasses. The apex of the prosthesis was measured with a Hertel exophthalmometer. The post-enucleation-syndrome was assessed by a 4 point scale by the investigators. They observed that post-enucleation-syndromes are significantly ($p < 0.01$) less pronounced in patients with orbital implants, also prosthesis motility is significantly ($p < 0.05$) larger. The width of the palpebral fissure and the

vertical difference of the eye axis is not significantly ($p > 0.05$) altered. They concluded that primary orbital implants allow for prevention of a post-enucleation-syndrome and a better functional and cosmetic outcome.

5. A simple algorithm for selection of implant size for enucleation and evisceration: a prospective study. Kaltreider SA, Lucarelli MJ.et al.

Ophthal Plast Reconstr Surg. 2002 Sep;18(5):336-41.

This prospective study tested a simple formula for selecting an implant size for patients undergoing enucleation, evisceration, and secondary implantation. The formula axial length-2 mm=implant diameter (subtract 1 mm from implant diameter for evisceration and for hyperopia) was tested by the outcome measures, superior sulcus deformity, enophthalmos, and volume of the prosthesis. Fifty-four patients undergoing primary or secondary implant surgery after enucleation or evisceration received implants based on the above formula. The volume of the eye, volume of the implant, volume of the prosthesis, and the total percent volume replacement were recorded for each patient. Outcome measures considered clinically acceptable were <2 mm enophthalmos and less than grade 1 superior sulcus deformity, which is defined as barely perceptible deepening of the medial superior sulcus. The average volume replacement was 101%; average prosthetic volume was 2.1 mL; average grade of superior sulcus deformity was 0.6; and average enophthalmos was 1.2 mm. They concluded that this formula allows 100% replacement of the

volume removed, leaves space for a prosthesis 1.5 to 2.5 mL, and eliminates clinically unacceptable superior sulcus deformity and enophthalmos in 85% of patients. Patients with a history of infection, radiation, buphthalmos, or large orbital fractures (15%) had residual superior sulcus deformity greater than grade 1 and enophthalmos > or =2 mm despite 100% volume replacement.

6. Comparison of artificial eye amplitudes with acrylic and hydroxyapatite spherical enucleation implants. Colen TP, Paridaens DA, et al Ophthalmology. 2000 Oct;107(10):1889-94.

This was a randomized, controlled trial aimed at comparing artificial eye amplitudes in patients who randomly received either a hydroxyapatite or an acrylic, scleral-covered spherical implant after enucleation. Eligible patients randomly received a hydroxyapatite or an acrylic,scleral-covered spherical orbital implant. Fourteen patients were fitted with a hydroxyapatite implant, and 16 were fitted with an acrylic implant. They measured horizontal and vertical saccadic amplitudes of both the artificial eye and the healthy eye using magnetic search coils technique. Saccadic amplitudes of the artificial eye were compared with the healthy eye of the patient. The amplitudes of the healthy eyes were compared with saccadic amplitudes of control participants. The interval from surgery to measurements was at least 3 months in all patients. Saccadic gain (artificial eye and eye amplitude divided by target amplitude) and saccadic symmetry (artificial eye amplitude divided by healthy eye amplitude)

were calculated. The main outcome measures were saccadic gain and saccadic symmetry. They observed that the gain in the healthy eyes of the patients was comparable with the gain of the control eyes. Saccadic symmetry was 1.0 in control participants. In patients, it was 0.334 in horizontal saccades and 0.577 in vertical saccades. However, saccadic symmetry did not differ significantly between the acrylic group and the hydroxyapatite group (P: > 0.1 for any saccadic direction). They concluded that when no motility peg is placed, acrylic and hydroxyapatite spherical implants yield comparable saccadic amplitudes of the artificial eye and artificial eye amplitudes were markedly more restricted horizontally than vertically.

6. Extrusion rate of silicone spherical anophthalmic socket implants. Nunery WR, Cepela MA,et al. Ophthal Plast Reconstr Surg.1993 Jun;9(2):90-5.

They analysed that the Frost-Lange technique which incorporates imbrication of recti muscles over an 18 mm spherical implant, and purse stringing of conjunctiva and Tenon's fascia in a single layered closure and reported that the technique has led to extrusion rates as high as 11.3% and superotemporal implant migration and poor prosthetic motility. They modified the technique which includes suturing recti muscles independently to a 20 mm spherical implant reinforced with autogenous fascia or preserved sclera and then closing Tenon's fascia and conjunctiva independently as separate layers. They observed that the extrusion rate during a 10 year study period was 0.84%

(1 of 119). There were no cases of implant migration, painful socket, and prosthetic motility was good. They recommend their technique modification to replace the traditional Frost-Lange technique.

7. Prosthesis motility with and without intraorbital implants in the anophthalmic socket. Smit TJ, Koornneef L et al. Br J Ophthalmol. 1991 Nov;75(11):667-70.

Ocular prosthesis motility was measured and compared in 15 patients with a primary baseball implant after enucleation of an eye, in 11 patients with a secondary baseball implant, in 12 patients with an Allen implant, and in 11 patients without any intraorbital implant. In all patients a noticeable lag of movement of the prosthetic eye was measured: in the extreme directions of gaze the excursions of the prosthesis were far less in comparison with the contralateral normal eye. For normal eye movement round the primary position of gaze, however, the prosthesis motility in the primary baseball and Allen implant group appeared to be sufficient to give a lifelike appearance. The average motility of the prostheses in these two groups did not differ. The motility in the secondary baseball group and in the group without an implant was evidently worse. In the last group the prosthesis motility was most impaired. They concluded that the insertion of an implant, even when inserted some time after the enucleation (a secondary implant), improves the motility of

the prosthesis markedly. They recommend the primary baseball implant as the correction of choice after enucleation.

8. Enucleation with unwrapped porous and nonporous orbital implants: a 15-year experience. Trichopoulos N, Augsburger JJ et al. Ophthal Plast Reconstr Surg. 2005 Sep;21(5):331-6.

This was a retrospective analysis of a series of 258 patients who received either an unwrapped nonporous spherical implant (n = 68) or an unwrapped porous spherical implant (n = 190) to find out the actuarial rates of migration of the implant and implant exposure. Median follow-up duration in this study was 37.6 months. Implant exposure occurred in 1 of the 68 nonporous implant cases (1.5%) and in 4 of the 190 porous implant cases (2.1%). This difference is not statistically significant (P = 0.85). In contrast, clinically significant implant migration occurred substantially more frequently in the patients who received a nonporous implant. The cumulative actuarial probability of implant migration at 60 months was 15.5% for the nonporous implants versus 0.7% for the porous implants. This difference was statistically significant (P = 0.0003). They concluded that orbital implant migration occurred in a significantly greater proportion of patients who received a nonporous implant than in those who received a porous implant. Implant exposure occurred at a low rate that was not significantly different in the two subgroups.

9. Tarsal strip procedure for correction of eyelid laxity and canthal Malposition in the anophthalmic socket. Anderson RL et al. Ophthalmology. 1981 Sep;88(9):895-903.

They studied that surgically anophthalmic sockets commonly have laxity of the lower eyelid, inferior displacement of the lower eyelid and lateral canthus, shallowing of the inferior fornix, and a deep superior sulcus and these deformities result in difficulty in prosthesis retention, pooling of tears and mucus, epiphora and lower eyelid irritation, and poor cosmesis with an appearance of facial asymmetry. The main anatomic deformity is a marked laxity and elongation of the lateral canthal tendon. The tarsal strip procedure is ideal for correcting or improving these deformities simultaneously with one simple procedure. They observed good results in 26 patients with surgically anophthalmic sockets in which the above procedure was utilized. They recommended the tarsal strip procedure not only to correct these conditions in anophthalmic sockets but in almost any condition where laxity of the eyelids or canthal malposition requires surgical correction.

10. Complications of orbital implants: a review of 542 patients who have undergone orbital implantation and 275 subsequent PEG placements. Shoamanesh A, Pang NK, Oestreicher JH. Orbit. 2007 Sep;26(3):173-82.

This was a retrospective chart review of 542 patients who underwent eviscerations, enucleations and secondary procedures by one surgeon to study the complications associated with three commonly used orbital implants, as well associated anophthalmic socket issues.. Approximately 60% of patients experienced complications prior to implant drilling, with discharge being the most prevalent (15.9%). Secondary procedures were associated with significantly greater complication rates prior to implant drilling. Silicone implants had significantly less pre-pegging pyogenic granuloma (P = 0.011) and hypo-ophthalmos (P = 0.042) than the other implant types. Seven implants had to be removed due to exposure. Implant drilling and peg placement were performed in 275 patients. Implant drilling complications were experienced by 67.4% of pegged patients, with a change in discharge from prior to pegging (27.2%) being the most prevalent. Plastic peg systems had a significantly higher incidence of complications than titanium systems. They concluded that the majority of orbital implantations involve complications, these being largely minor ones which resolve spontaneously or are easily treated. Secondary implant procedures involve a higher likelihood of complications. Silicone implants have the smallest amount of complications. Should patients decide to undergo pegging, evidence sides strongly for the use of a titanium peg and sleeve system over the other peg types. Implant removal is a rare event; occurring in 1.3% (n = 7) of the study population.

11: Comparison between motility of biointegratable and silicone orbital implants. González-Candial M, Umaña MA, Galvez C, Medel R, Ayala E. Am J Ophthalmol. 2007 Apr;143(4):711-2.

A retrospective comparative study was conducted to determine any difference in motility between biointegratable orbital implants and silicone orbital implants in patients undergoing ocular evisceration. They compared motility measuring the excursion of a mark on the conjunctiva at the center of the implant in eviscerated patients with silicone implants and biointegratable implants after same evisceration technique. Silicone implants had 0.5-mm increased movement in inferior and medial duction compared with biointegratable implants. The later had 0.1 mm of increased movement compared with silicone implants in lateral gaze. The greatest difference was in superior gaze, in which silicone implants had 1.5 mm more excursion than biointegratable implants. No significant difference was observed in horizontal and vertical movements between both groups. They concluded that, there does not seem to be any advantage, in terms of motility, in using biointegratable implants if "pegging" is not planned. Further studies are required.

12.Synthetic hydroxyapatite-based integrated orbital implants: A human pilot trial: Kundu B, Sinha MK, Mitra S, Basu D.. Indian J Ophthalmol 2005;53:235-241

The study evaluated the efficacy of two different models of synthetic HAp with 75% porosity and pore sizes ranging from 100 to 300 mm. in 25 patients. The postoperative performances of these implants were evaluated in respect to the degree of volume replacement (implant + prosthesis), presence/absence of lagophthalmos and lower eye-lid laxity, status of socket and fornices. Magnetic resonance imaging assessed the stability of the implants within the socket and progressive fibro-vascularisation within the porous scaffold as a function of time. Finally, motility of the implants as well as the prostheses (horizontal movements by Lister Perimeter) and subjective cosmetic results (qualitative) were also evaluated. During the 2.5 years of follow-up study, no significant postoperative complications were noticed. One case, showed an anterior implant exposure of 3-4 mm, and was managed with donor scleral patch graft and one case of conjunctival thinning was corrected by re-suturing the conjunctival dehiscence. Fourteen of the 25 patients had a very good movement of the prostheses (> 20° horizontal movement) and the other 11 patients had a fair motility (10 - 20°). The degree of volume replacement (with prosthesis) was found to be very good in 21 patients and fair in other 4 patients. All patients reported cosmetic satisfaction. They concluded that synthetic HAp-based integrated orbital implants with this modified design were found clinically safe and cosmetically acceptable.

AIMS AND OBJECTIVES

1. To study the demography of patients receiving orbital implants following enucleation and evisceration.

2. To evaluate the efficacy of silicone ball orbital implant in primary enucleation and evisceration .

3. To study the complications related to the use of silicone orbital implants.

MATERIALS AND METHODS

A prospective, descriptive, randomized interventional study on the outcome and complications of enucleation and evisceration surgeries using silicone orbital implants was conducted in the Department of Orbit, Oculoplasty and Ocular oncology, Aravind eye Hospital, Madurai.

The study was conducted from March 2006 to August 2007. The patients who underwent any of the above mentioned surgical procedures during the specified were enrolled based on the inclusion and exclusion criteria.

Inclusion criteria:

1. Patients having any of the following symptoms :

   1.1 Penetrating trauma causing blindness

   1.2. A blind eye with severe deformation of the globe

   1.3. Painful blind eye due to non malignant disease

   1.4. Pthisis bulbi

2. Patients who were willing to participate in the study and ensured good compliance.

Exclusion criteria :

Blind or disfigured eye secondary to :

1. Complex orbital trauma

2. Primary malignant ocular tumors

3. Secondary orbital metastatic tumors.

4. Systemic malignancy

5. Contracted socket - grade 2 or more.

Clinical evaluation of the cases:

All the patients involved in the study were evaluated in detail prior to the surgery.

The patients' particulars like name , age, sex, address, economic status were documented.

Pre- operative evaluation included thorough history taking pertaining to ocular and general systemic pathology and trauma which may influence the outcome of the surgery A detailed history was taken regarding the cause of blindness, the presence of pain,and the duration of the symptoms.. The patients were also enquired about h/o orbital trauma, h/o neoplasm, h/o medical therapy for neoplasm, h/o radiotherapy which could influence the outcome of the surgery. Both the eyes of the patient were examined and the indication for the surgery was established. The socket of the affected eye was examined to rule out lid malpositions, forniceal abnormalities and contracted sockets which could again influence the outcome of the study. The axial length of the normal

eye was measured to have a rough estimate of the size of the implant that could be placed.

Preanaesthetic medication and anaesthetist ‘s opinion was obtained in all cases. The investigations included hemoglobin %, bleeding time , clotting time, tests to rule out diabetes, blood pressure recording, renal parameters like blood urea, serum creatinine, serum electrolytes, and electrocardiography. All the surgeries were performed under general anaesthesia. The choice of the anaesthetic drug depended on the systemic status of the patient.

The surgical technique:

Enucleation with silicone implant:

Under general anaesthesia , the patient is prepared and draped for surgery. After ensuring the correct eye to be operated, the eye is exposed to the operating sterile field.

The eyelids are retracted with a speculum. A 360 degree peritomy is made at the limbus to preserve as much conjunctiva as possible and to permit adequate fornices in the anophthalmic socket. Each rectus muscle is then isolated by passing a muscle hook behind it from either side. The muscle is ligated with an absorbable suture like, 6-0 vicryl which is passed through the muscle in a serpentine fashion, approximately 2 mm behind its insertion on the globe. The suture is locked on each side of the muscle. The muscle is then

severed between the suture and the globe. The ends of the suture can then be used to retract the muscle away from the globe. Similarly the superior and inferior oblique muscles are isolated.

A smooth instrument e.g. muscle hook is passed along the globe to ensure that Tenon's capsule is completely removed from the globe in all areas upto the optic nerve. The eyeball is luxated out by speculum / or clamp and enucleation scissors , the optic nerve is cut as far as possible and the globe is removed. Hemostasis is achieved by pressing a piece of gauze to promote vasoconstriction and by using bipolar cautery to the bleeding vessels so as to prevent or control bleeding. In case of excess bleeding , bone wax can be used. The Tenon's capsule is separated from the conjunctiva using blunt dissection.

The implant which is to be used is wrapped with donor sclera, before starting the enucleation. This wrapped implant is placed is placed within the socket. The orbital fat should be seen through this posterior opening in the Tenon's capsule. The implant is placed through this opening into the orbital fat (i.e.. placing the implant posterior to the posterior Tenon's capsule). The muscles are then attached in the following manner. The medial rectus is attached to the medial aspect of the sclera wrapped implant . Similarly, in a spiral pattern the lateral rectus is attached to the lateral aspect, the superior rectus is attached to the upper aspect and the inferior rectus to the lower aspect of the implant .

The anterior aspect of the tenon's capsule is closed with interrupted 6-0 vicryl sutures. The conjunctiva is closed with running continuous vicryl sutures.

An antibiotic ointment is applied to the socket. A transparent conformer with several small 2 mm sized holes is placed in the socket. The size of the conformer should permit the eye to be closed without any tension on the fornices. The eye is closed and patched firmly with 2- 3 eye pads.

Evisceration with silicone implant:

Under general anaesthesia, the patient is prepared and draped for surgery. After ensuring the correct eye to be operated, the eye is exposed to the operating sterile field. The eyelids are retracted with a speculum. A 360 degree peritomy is made at the limbus to preserve as much conjunctiva as possible and to permit adequate fornices in the anophthalmic socket. Tenon's capsule and the conjunctiva are undermined posteriorly towards the insertion of the rectus muscles. The anterior chamber is entered at the 12 o 'clock position and the cornea is completely excised with scissors. An evisceration spoon is used and the contents of the globe are delivered in toto by scooping the specimen out from behind with the evisceration spoon. Occasionally profuse bleeding from the central retinal artery and vortex vessels occurs, which can be controlled with direct pressure with gauze packing ,application of minimum direct cautery to the bleeding points. Once the field is bloodless the remaining shreds of uveal pigment are removed with forceps and curette or a moistened gauze. The scleral

cavity is irrigated with povidone iodine solution and the cavity is re-inspected meticulously to ensure that all pigmented tissue is removed. Small linear relaxing incisions are made at the 3 and 9 o' clock positions with care taken to avoid the insertion of the rectus muscles. These relaxing cuts can also be placed at the oblique quadrants, alternatively. The intraocular implant of the desired size is inserted and the scleral wound is approximated or can be closed by overlapping the wound edges in a horizontal line, using multiple mattress sutures of 6-0 vicryl sutures. Tenon's capsule is re-approximated with interrupted 6-0 vicryl sutures. The conjunctiva is closed with running vicryl sutures.

An antibiotic ointment is applied to the socket. A transparent conformer with several small 2 mm sized holes is placed in the socket. The size of the conformer should permit the eye to be closed without any tension on the fornices. The eye is closed and patched firmly with 2- 3 eye pads.

Post operative evaluation:

The patient's eye was examined on the first post operative day to detect complications like hemorrhage, wound dehiscence, exposure of the implant. Antibiotic eye ointment was applied and analgesics were given and the patient was asked to continue them for 2 weeks. The patient was reexamined at the end of 15 days, 30 days , and 3 months. The patients were advised to fit custom

made prosthesis 4 to 6 weeks post operatively after ensuring adequate wound healing by the doctor.

The outcome and the cosmesis:

The post operative performance of the eye was analysed after fitting the prosthesis on the basis of:

1. **The volume replacement –**

The degree of volume replacement (with implant and prosthesis) was assessed quantitatively by proptometry , while the qualitative assessment was performed by observing the superior sulcus deformity. Using a Luedde's exophthalmometer the distance between the lateral orbital rim and the apex of the cornea (in the normal eye) was measured. The distance between the lateral orbital rim and and the tip of the prosthesis was measured. The diference between the the two measurements was calculated. A difference of 2 mm or less was considered as good volume replacement. The presence of lagophthalmos or ptosis was also documented.

2. The ocular motility

The ocular motility was based on Kestenbaum's limbal excursion method. The readings were documented as:-

a) no movements	:	**-4 (poor)**
b)25 % movements	:	**-3 (fair)**
c)50 % movements	:	**-2 (good)**
d)75 % or more	:	**-1 (excellent)**

Subjective evaluation:

The patients' complaints such as pain , pain related to ocular movements, irritation, and discharge were also considered. Last but not the least , the patient was enquired whether he or she was happy and satisfied by the outcome of the surgical procedure.

RESULTS

Based on the exclusion and inclusion criteria, 65 cases were taken up for the study.

Demographic study:

1. Age distribution of cases

Age

Age	Minimum	Maximum	Mean
Age	5	72	29.85

Age group

Age group (in years)	Frequency	Percent
<20	11	16.9
20-40	41	63.1
40-60	11	16.9
>60	2	3.1
Total	**65**	**100**

Most of the patients in the study belonged to the age group 20 to 40 years. The minimum age was 5 years and the maximum age was 72 years. The mean age was 29.85 years with a standard deviation of 13.766.

2. The gender

Age Group and Gender Cross tabulation

Age group	Gender		Total
	Male	Female	
<20	6	8	11
20-40	29	15	41
40-60	6	5	11
>60	1	1	2
Total	**42**	**23**	**65**

Of the 65 patients, 42 were males (64.6%) and 23 were females (35.4%).

3. The laterality

Laterality	Frequency	Percent
Right Eye	29	44.6
Left Eye	36	55.4
Total	**65**	**100.0**

Of the 65 patients, 29 of them had involvement of the right eye and 36 of them had involvement of the left eye.

4. The indications for surgery

Indications for surgery	Frequency	Percent
Penetrating Trauma Causing Blindness	4	6.2
Severe Deformation of the globe	31	47.7
Painful blind eye due to nonmalignant cause	11	16.9
Pthisis Bulbi	19	29.2
Total	**65**	**100.0**

47.7% of the patients underwent surgery due to severe deformation of the globe. 29.2% of them had pthisis bulbi. 16.9% of the patients suffered due to a painful blind eye due to nonmalignant disease (like endophthalmitis / panohthalmitis induced blindness, secondary glaucoma, etc). The remaining 6.2 % underwent surgery for penetrating trauma.

5. The type of surgery

Type of surgery	Frequency	Percent
Enucleation with implant	58	89.2
Evisceration with implant	7	10.8
Total	**65**	**100.0**

89.2% of the patients in the study underwent enucleation with silicone implant and 10.8% underwent evisceration with silicone implant. 6 out of the 7 patients underwent evisceration because they had severe deformation of the globe.

6. The size of the implant

Implant size	Frequency	Percent
14mm	7	10.8
16 mm	48	73.8
18 mm	10	15.4
Total	**65**	**100.0**

A 16 mm implant was used in most of the cases (48 cases). In the remaining 17 patients, 10 patients had a 18 mm implant and 7 of them had a 14 mm implant.

7. Post operative complications

Complications	Frequency	Percent
1. Conjunctival dehiscence	3	4.6
2. Conjunctival granuloma	1	1.5
3. Socket contracture grade 1 and symblepharon	1	1.5
4. Retention cyst	1	1.5
5. Implant exposure	1	1.5
6. Implant extrusion	3	4.6

Of the 65 patients who underwent the surgery, 10 of them had complications. 3 patients had conjunctival dehiscence. One patient developed a conjunctival granuloma and another a retention cyst. 3 patients had implant extrusion. There was one case of implant exposure. The above complications were managed as described below.

Complications	Additional surgery
1. Conjunctival dehiscence	Conjunctival resuturing
2. Conjunctival granuloma	Granuloma excision
3. Socket contracture grade 1 and symblepharon	Fornix deepening suture and symblepharon release
4.Retention cyst	Needling
5.Implant exposure	Scleral patch graft
6.Implant extrusion	
Case 1	Repeat surgery using a smaller implant and a scleral patch graft
Case 2	Socket debridement and broad spectrum antibiotics
Case 3	Dermis fat graft

8. Fitting of the prosthesis

Prosthesis fitting	Frequency	Percent
Prosthesis	59	90.8
No prosthesis	6	9.2
- due to complication	4	6.1
- due to lack of follow up	2	3.1

59 patients were fitted with either custom made or stock prosthesis. Of the remaining 6 patients, 4 of them were not fitted with prosthesis because of complications and 2 of them did not come for follow up.

9. Type of prosthesis

Prosthesis	Frequency	Percent
Custom fit	41	69.5
Stock fit	18	30.5

Of the 59 patients, 41 patients were fitted with custom made prosthesis. The others preferred to use stock prosthesis.

10. Volume replacement

Volume Replacement	Frequency	Percent
No difference	43	73
<2 mm	11	18.6
>2mm	5	8.4

Of the 59 patients, the volume replacement was poor in 5 cases. The remaining 54 patients (91.6%) either had no volume deficit or had less than or equal to 2 mm difference which was considered as good cosmesis.

11. Ocular motility

Ocular Motility	Frequency	Percent
50% movements	37	62.7
25 % movements	6	10.2
No movement	16	27.1

37 patients had nearly 50% ocular motility. Of the remaining patients, 6 of them had atleast 25 % motility while the others had no ocular movement.

12. Subjective evaluation of the procedure

12.1 Discomfort

Discomfort		Frequency	Percent
Pain	Present	5	7.7
	Absent	54	83.1
Discharge			
	Present	2	3.1
	Absent	57	87.7
Total		5	7.7

Of the 59 patients who were fitted with prosthesis, 5 of them experienced discomfort either in the form of pain or discharge. The rest were comfortable.

12.2 Cosmesis.

Cosmesis	Frequency	Percent
Satisfied	43	72.9
Not satisfied	16	27.1

43 out of the 59 patients were happy with the outcome of the procedure. The others included patients who needed a secondary procedure to correct the lid laxity and those who preferred to use a stock prosthesis.

12.3 Lower eyelid laxity

Lower eyelid laxity	Frequency	Percent
Present	18	30.5
Absent	41	69.5

18 out of the 59 patients had lower lid laxity and the rest had a normal lower lid anatomy.

12.4. Additional surgery after prosthesis fitting

For Lid laxity	Frequency	Percent
Lateral tarsal strip	6	10.1
Lateral tarsorrhaphy	2	3.3
Lateral tarsal strip with tarsoraphy	2	3.3
Total	**10**	**16.9**

After fitting the prosthesis there were 10 patients who required and desired an additional surgery for their lower lid laxity.

DISCUSSION

The management of an anophthalmic socket is a challenge to the treating ophthalmologist. The restoration of both comfort and cosmesis is extremely important to the patient who is already suffering due to the psychological trauma following the loss of an eye. The role of the ophthalmologist begins from discussing the preparation for surgery and the patient's post operative appearance, upto providing emotional assistance in returning the patient to a productive life. There are varied options of treating these patients and the current trend is the usage of orbital implants during primary enucleation or evisceration. The choice of implant depended on the cost the outcome and the experience of the surgeon.

The current study was carried out over a period of 18 months on 65 patients to determine the efficacy of silicone ball orbital implants. This case series have shown favourable results of the silicone ball implant. Analyzing the demographic details in our study, it is seen that most of our patients (62.1%) were between 20 to 40 years of age. The male patients were predominant group in the study. The above parameters could vaguely suggest the higher incidence of ocular trauma in the males and the interest in retaining good cosmesis in the occupationally and socially active group of our society.

Regarding the performance of these implants, the volume replacement was 91.6% (54 out of the 59 patients), the remaining had inadequate volume either because of the use of a smaller implant or the patient preferred to use a stock fit prosthesis. The custom fit prosthesis has the advantage of adding a little more volume to the orbit thus achieving better volume replacement. The empirical formula described by Kaltreider[70] can be used only as a guide to the size of the implant. It is calculated only for the globe's axial length and does not include the retrobulbar volume (which includes the orbital fat and connective tissue). It is well known that orbital fat atrophy occurs in long standing cases of phthisis bulbi (19 cases).

The ocular motility was good in 62.7 % of the patients, and fair in 10.2%. The rest had unsatisfactory motility due to an overweight custom fit prosthesis, a poorly fit stock prosthesis, a smaller implant, and different surgeons although the same technique. The prosthetic motility is determined by a variety of factors. The size, shape and weight of the prosthesis affect the ultimate movement of the prosthesis. Larger, heavier prosthesis generally demonstrate less movement. Superior augmentation of the prosthesis to correct ptosis or a deep superior sulcus also limits motility. Although these factors somewhat dependent on the spherical implant size, they are independent of the implant material. Extraocular muscle function is transmitted via the scleral capsule of the implant to the overlying Tenon's fascia and the conjunctiva. The

nonpegged prosthesis are indirectly coupled to the implant via the surface tension at the prosthetic- conjunctival interface[71]. In a randomized control trial conducted by Colen TP, Paridaens DA, et al[72], it was observed that in the absence of motility pegs, nonporous (acrylic) and porous (hydroxyapatite) spherical implants yield comparable saccadic amplitudes of the artificial eye and artificial eye amplitudes were markedly more restricted horizontally than vertically. Custer et al[71] in their longitudinal cohort study of 107 patients also found no difference in motility between hydroxyapatite and nonporous scleral covered implants. Coupling the prosthesis to a porous implant with a motility peg appears to improve prosthetic motility, but there are few available data in the literature that document the degree of the improvement. Larger implants seem to provide improved implant motility, which should result in more dramatic prosthetic movement. But excessively large implants may increase the risk of extrusion, make prosthesis fitting difficult, or result in patient discomfort. Ideally, sufficient space must remain in the socket to allow fitting of the prosthesis with atleast 2 ml volume and approximately 4 mm central thickness[73].

In our study, the patients satisfaction was evaluated based on the discomfort, and the overall satisfaction of their surgical outcome. There were only 5 patients who experienced discomfort and the majority 87.7 % were comfortable in all the follow ups. Regarding the overall satisfaction, nearly

73% were happy. The rest (16 patients) were unsatisfied either because they had a cosmetic deficit like lower lid laxity, or were fitted with stock prosthesis due to economic problems. All the patients who desired a corrective procedure underwent either a lateral tarsal strip, lateral tarsorrhaphy, or both as decided by the surgeon. These patients were also happy at the end of the corrective procedure, thus increasing the overall satisfaction rate to 89.9 %. The major complication encountered in our study were exposure and extrusion of the implant. There were 3 cases of extrusion (4.6%) and one case of exposure (1.5%). All the 4 cases of extrusion and exposure were due to infection of the wound. The extrusion/exposure rates in other studies were:

S No.	Authors	Type of implant	Exposure rate
1.	Su GW, Yen MT. et al.	Unpegged implants	3.2%
		Porous polyethylene	1.8%
		Hydroxyapatite	1.21%
		Nonporous	0.03%
2.	Li T, Shen J, Duffy MT. et al.	Porous polyethylene	9%
3.	Nunery WR, Cepela MA, et al.	Silicone	0.84%
4.	Trichopoulos N, Augsburger JJ et al.	Acrylic	1.5%
		Porous polyethylene	2.1%
5.	Christmas NJ, Gordon CD, Murray TG, et al.	Hydoxyapatite	1.1%
		Acrylic	2.6%
		Silicone	0
6.	**Our study**	Silicone	6%

CONCLUSION

In our study, 65 patients who underwent primary enucleation or evisceration were fitted with silicone ball orbital implants during March 2006 to February 2007. Each of these patients were followed over a period of 6 months post operatively.

1. The age distribution of patients were such that the maximum number of patients (69.1%) were in the age group of 20 to 40 years.

2. Males constituted 64.5% while females constituted 34.5%.

3. The major indication in our study patients was severe deformation of the globe (e.g. staphyloma) (47.7%), followed by pthisis bulbi (29.2%).

4. Most of the patients underwent primary enucleation with silicone ball implant (89%) while only were the rest (11%) underwent evisceration with silicone implant.

5. Of the 65 patients who underwent the surgery, 10 of them had complications. There were three cases of implant extrusion and one case of implant exposure.

6. After fitting the prosthesis, the good volume replacement was achieved in 91.6%, and, the ocular motility was good in 62.7% of the patients.

7. Nearly 90% of the patients were satisfied with their surgical outcome.

Considering the overall picture, it is evident that the use of silicone ball orbital implant post enucleation or evisceration is definitely beneficial to the patient in terms of improving his quality of life. The best implant to use remains a matter of controversy and surgeon preference. Implant costs, hospital budget restraints, and marketing pressure all influence which implant is favored. Current clinical evidence is not sufficient to suggest either that porous implants are superior to non-porous implants, or that one material is more suited to the application than another. Future developments in this field require randomized controlled clinical trials with extensive follow-up to decide the best implant.

BIBLIOGRAPHY

1. Baylis H,Shorr N: Evisceration,enucleation and exenteraration in Mccord JR (ed) Oculoplastic surgery, NY,1981 pp 313-326.
2. Dortzbach RK, Woog JJ: Choice of procedure: enucleation, evisceration, or prosthetic fitting over globes. Ophthalmology 92:1249–55, 1985.
3. Kennedy RE. Enucleation, evisceration and exenteration. In Iliff, NT, ed: Complication in ophthalmic surgery. NY, 1983, Churchill Livingstone.
4. Mules PH. Evisceration of the globe, with artificial vitreous. Trans Ophthalmol Soc U K. 1885;5:200–206.
5. Tyers AG,Collins JR. Orbitalimplants and post enucleationsocket syndrome. Trans Ophthalmol Soc UK 1982;102:90-2
6. Smit TJ, Koornneef L, Zonneveld FW, et al: Computed tomography in the assessment of the postenucleation socket syndrome. Ophthalmology 97:1347–51, 1990.
7. Soll DB: Evolution and current concepts in the surgical treatment of the anophthalmic orbit. Ophthalmic Plast ReconstrSurg 2:163–71, 1986
8. Soll DB, Soll SM, Asbell RL : Evolution and current concepts in the treatment of the anophthalmic socket. In Nesi FA, Lisman RD, Levine MR(eds): Smith's ophthalmic plastic and reconstructive surgery. St Louis, Mosby, 1987.

9. Kohn R. Acquired anophthalmos and related disorders. In Kohn R: Textbook of ophthalmic plastic and reconstructive surgery. Philadelphia, Lea and Febiger, 1988.
10. Migliori ME: Evaluation and management of the anophthalmic socket. In Bosniak S: Principles and practice of ophthalmic plastic and reconstructive surgery. Philadelphia, W.B. Saunders, 1996.
11. Korneeef L. Spatial aspects of orbital musculofibrous tissues in man. Amsterdam and Lisse, Swets and Zellinger, BV, 1977
12. Soll DB: The anophthalmic socket. Ophthalmology 89: 407–23, 1982.
13. Sami D, Young S, and Petersen R. Perspective on Orbital Enucleation Implants. Major review. Survey of ophthalmology Volume 52 , 2007.
14. Luce CM. A short history of enucleation. Int Ophthalmol Clin. 1970;10:681–687.
15. Grinsdale H. Note on early case of Mules' operation. Br J Ophthalmol. 1919;8:452.
16. Soll DB. Expandable orbital implants. In: Turtz A ed. Proc Cent Symp. Manhattan Eye, Ear, and Throat Hospital, Vol I: Ophthalmology. St Louis: Mosby; 1969:197–202
17. Gougelmann HP. The evolution of the ocular motility implant. Int Ophthalmol Clin. 1976;10:689–711.
18. Allen TD. Guist's bone spheres. Am J Ophthalmol. 1930;13:226.

19. McCoy LL. Guist bone spheres. Am J Ophthalmol. 1932;15:960.
20. Spaeth EB. The Principles and Practices of Ophthalmic Surgery. Malvern, PA: Lea and Febiger; 1941:127–142.
21. Ruedemann AD. Plastic eye implants. Am J Ophthalmol. 1946;29:947.
22. Cutler NL. A universal type integrated implant. Am J Ophthalmol. 1949;32:253–258.
23. Allen JH, Allen L. A buried muscle cone implant. Development of a tunneled hemispherical type. Arch Ophthalmol. 1950;43:879–890.
24. Allen LH, Ferguson EC III, Braley AE. A quasi-integrated buried muscle cone implant with good motility and advantages for prosthetic. lling. Trans Am Acad Ophthalmol Otolaryngol. 1960;64:272–286.
25. Spivey BE, Allen LH, Burns CA. The Iowa enucleation implant. A ten year evaluation of techniques and results. Am J Ophthalmol. 1969;67:171–188.
26. Jordan DR, Anderson RL, Nerad JA, et al. A preliminary report on the universal implant. Arch Ophthalmol. 1987;105:1726–1731.
27. Jordan DR, Anderson RL. The universal implant as an evisceration implant. Ophthal Plast Reconstr Surg. 1997;13:1–7.
28. Hornblass A, Biesman BS, Eviatar JA. Current techniques of enucleation: a survey of 5,439 intraorbital implants and a review of the literature. Ophthal Plast Reconstr Surg. 1995;11:77–86.

29. Beard C: Remarks on historical and newer approaches to orbital implants. Ophthalmic Plast Reconstr Surg 11:89–90, 1995

30. Allen L: The argument against imbricating the rectus muscles over spherical orbital implants after enucleation. Ophthalmology 90:1116-20,1983

31. Hornblass A, Biesman BS, Eviatar JA: Current techniques of enucleation: a survey of 5,439 intraorbital implants and a review of the literature. Ophthalmic Plast Reconstr Surg 11:77–86; discussion 87–8, 1995.

32. Perry AC: Integrated orbital implants. Adv Ophthalmic Plast Reconstr Surg 8:75–81, 1990.

33. Perry AC: Hydroxyapatite: the vascularizing integrated orbital implant, in Stephenson CM (ed): Ophthalmic, Plastic, Reconstructive, and Orbital Surgery. Boston, Butterworth- Heinemann, 1997, pp 463–79.

34. Shields CL, Shields JA, Eagle RC Jr, De Potter P: Histopathologic evidence of fibrovascular ingrowth four weeks after placement of the hydroxyapatite orbital implant. Am J Ophthalmol 111:363–6, 1991.

35. Sires BS, Dortzbach RK, Holds JB: Theoretical considerations in the placement of hydroxyapatite orbital implants [letter]. Ophthalmic Plast Reconstr Surg 13:147–51, 1997.

36. Sires BS, Holds JB, Archer CR: Postimplantation density changes in coralline hydroxyapatite orbital implants. Ophthalmic Plast Reconstr Surg 14:318–22, 1998.
37. Sires BS, Holds JB, Archer CR: Variability of mineral density in coralline hydroxyapatite spheres: study by quantitative computed tomography. Ophthalmic Plast Reconstr Surg 9:250–3, 1993.
38. Sires BS, Holds JB, Archer CR, et al: Histological and radiological analyses of hydroxyapatite orbital implants in rabbits. Ophthalmic Plast Reconstr Surg 11:273–7,1995.
39. Rubin PA, Popham JK, Bilyk JR, Shore JW: Comparison of fibrovascular ingrowth into hydroxyapatite and porous polyethylene orbital implants. Ophthalmic Plast Reconstr Surg 10:96–103, 1994.
40. Goldberg RA, Dresner SC, Braslow RA, et al: Animal model of porous polyethylene orbital implants. Ophthalmic Plast Reconstr Surg 10:104–9, 1994.
41. Karesh JW, Dresner SC: High-density porous polyethylene (Medpor) as a successful anophthalmic socket implant. Ophthalmology 101:1688–95; discussion 1695–6, 1994.
42. Jordan and Klapper: Surgical Techniques in Enucleation. The Role of Various Types of Implants and the Efficacy of Pegged and Nonpegged Approaches. Int Ophthal Clin:109-134.

43. Soll DB: Enucleation surgery: a new technique. Arch Ophthalmol 87:196–7, 1972.

44. Nunery WR, Hetzler KJ: Enucleation, in Hornblass A (ed): Oculoplastic, Orbital, and Reconstructive Surgery, Vol. Baltimore, Williams & Wilkins, 1990, ed 1, pp 1200–1220.

45. Beaver HA, Patrinely JR, Holds JB, Soper MP: Periocular autografts in socket reconstruction. Ophthalmology 103:1498–502, 1996.

46. Naugle TC, Lee AM, Haik BG, et al: Wrapping hydroxyapatite orbital implants with posterior auricular muscle complex grafts. Am J Ophthalmol 128:495–501, 1999.

47. Dutton JJ. Advances and controversies in ophthalmic plastic surgery: enucleation and evisceration. The 1998 American Academy of Ophthalmology Annual Meeting, New Orleans, LA, November 10, 1998.

48. Naugle TC Jr, Fry CL, Sabatier RE, Elliott LF: High leg incision fascia lata harvesting. Ophthalmology 104:1480– 1997.

49. Jordan DR, Allen LH, Ells A, et al: The use of Vicryl mesh (polyglactin 910) for implantation of hydroxyapatite orbital implants. Ophthalmic Plast Reconstr Surg 11:95–9, 1995.

50. Moshfeghi et al: Enucleation: Major review. Surv Ophthalmol 44 (4):281-300, 2000.

51. Kaltreider SA, Jacobs JL, Hughes MO: Predicting the ideal implant size before enucleation. Ophthalmic Plast Reconstr Surg 15:37–43, 1999.
52. Patel BC, Sapp NA, Collin R: Standardized range of conformers and symblepharon rings. Ophthalmic Plast Reconstr Surg 14:144–5, 1998.
53. Schaefer DP, Rocca RCD: Enucleation, in Nesi FA, Lisman RD, Levine MR (eds): Smith's Ophthalmic Plastic and Reconstructive Surgery. St. Louis, Mosby, 1998, ed 2, pp 1015–1052.
54. Schaefer DP, Rocca RCD: Enucleation, in Nesi FA, Lisman RD, Levine MR (eds): Smith's Ophthalmic Plastic and Reconstructive Surgery. St. Louis, Mosby, 1998, ed 2, pp 1015–1052.
55. Meltzer MA: Complications of enucleation and evisceration: prevention and treatment. Int Ophthalmol Clin 32: 213–33, 1992.
56. Lyon DB, Dortzbach RK: Enucleation and evisceration, in Shingleton BJ, Hersh PS, Kenyon KR (eds): Eye Trauma. St. Louis, Mosby-Year Book, Inc., 1991, pp 354–367.
57. Lyon DB, Dortzbach RK: Enucleation and evisceration, in Shingleton BJ, Hersh PS, Kenyon KR (eds): Eye Trauma. St. Louis, Mosby-Year Book, Inc., 1991, pp 354–367.
58. Guberina C, Hornblass A, Smith B: Pitfalls of autogenous lipodermal implantation to the orbit. Ophthalmic Plast Reconstr Surg 3:65–70, 1987.

59. Oberfeld S, Levine MR: Diagnosis and treatment of complications of enucleation and orbital implant surgery. Adv Ophthalmic Plast Reconstr Surg 8:107–17, 1990.

60. Schaefer DP: Evaluation and management of the anophthalmic socket and socket reconstruction, in Nesi FA, Lisman RD, Levine MR (eds): Smith's Ophthalmic Plastic and Reconstructive Surgery. St. Louis, Mosby–Year Book, Inc., 1998, ed 2, pp 1079–1124.

61. Rose GE, Sigurdsson H, Collin R: The volume-deficient orbit: clinical characteristics, surgical management, and results after extraperiorbital implantation of Silastic block. Br J Ophthalmol 74:545–50, 1990.

62. Migliori ME: Evaluation and management of the anophthalmic socket, in Bosniak S (ed): Principles and Practice of Ophthalmic Plastic and Reconstructive Surgery, Vol. II. Philadelphia, W.B. Saunders Company, 1996, pp 1105–1126.

63. Stasior OG, Roen JL: Traumatic enophthalmos. Ophthalmology 89:1267–73, 1982.

64. Bartlett RE: Plastic surgery for the enucleation patient. Am J Ophthalmol 61:68–78, 1966.

65. Laiseca A, Laiseca D, Laiseca J, Laiseca J Jr: Correcting superior sulcus deformities. Adv Ophthalmic Plast Reconstr Surg 8:229–42, 1990.

66. Smith B, Lisman RD: Use of sclera and liquid collagen in the camouflage of superior sulcus deformities. Ophthalmology 90:230–5, 1983.

67. Leone CR Jr: Correction of superior sulcus defects after enucleation. Adv Ophthalmic Plast Reconstr Surg 8:209– 13, 1990.

68. Nunery WR, Cepela MA, Heinz GW, et al: Extrusion rate silicone spherical anophthalmic socket implants. Ophthalmic Plast Reconstr Surg 9:90–5, 1993.

69. Shields CL, Shields JA, De Potter P: Hydroxyapatite orbital implant after enucleation: experience with initial 100 consecutive cases. Arch Ophthalmol 110:333–8, 1992.

70. Kaltreider SA, Lucarelli MJ.et al. A simple algorithm for selection of implant size for enucleation and evisceration: a prospective study. Ophthal Plast Reconstr Surg. 2002 Sep;18(5):336-41.

71. Custer LP,Trinkaus KM, Fornoff J. Comparative motility of hydroxyapatite and allopalstic enuclaeation implants.. Ophthalmology 1999;106:513-516.

72. Colen TP, Paridaens DA, et al . Comparison of artificial eye amplitudes with acrylic and hydroxyapatite spherical enucleation implants. Ophthalmology 2000 ,107(10):1889-94.

73. Tyers AG,Collins JRO. Basebakll orbital implants: a review of 39 patients. Br J Ophthalmol 1985;69:438-442.